

U.S. Patent, Application No. 10/516,558
Amendment dated January 11, 2008
Reply to Office Action dated October 11, 2007

AMENDMENTS TO THE DRAWINGS:

Please replace Figure 12, with the amended Figure 12 depicted in the attached Replacement Sheet.

The attached sheet of drawings(s) includes changes to Fig. 12. This sheet replaces the original Fig. 12. In Fig. 12, previously omitted sequence identifiers have been added.

Attachment: Replacement Sheet

Annotated Sheet Showing Changes

ARGUMENTS/REMARKS

Continued examination and favorable reconsideration are respectfully requested.

Claims 1-5, 8-16, and 18-26 are pending in this application. Claims 1-3, 11-16, and 18-26 are withdrawn from consideration. By this Amendment, claims 4-5 and 8-10 have been amended and claims 6-7 and 17 have been canceled.

Priority Document

At page 2, item 6, of the Office Action, the Examiner has acknowledged receipt of papers submitted under 35 U.S.C. §119(a)-(d), which papers have been placed of record in the file. The Examiner recognizes a priority date of January 30, 2003. The Examiner indicates that because the priority of the instantly claimed invention is based on Japanese Application Nos. 2002-161400 and 2002-214978, and translations have not been provided, the Examiner is unable to recognize an earlier priority date. The Examiner suggests that Applicants submit a translation of the priority documents and to point to page and line where support can be found establishing an earlier priority date.

In response, English translations are not required for claiming priority. According to MPEP § 201.15, the actual merits of an applicant's claim of priority is considered by the Examiner only when a reference is found with an effective date between the date of the foreign filing and the date of filing in the United States. None of the publication dates of the references cited by the Examiner appears to fall within this range. As such, the priority dates of the Japanese applications should be recognized.

Objection to the Specification and Drawings

At page 3, item 7, of the Office Action, the Examiner objected to the specification and drawings for improper disclosure of amino acid sequences without a respective sequence identifier, i.e., SEQ ID NOs: see p. 38, lines 24-26, Fig. 12, and Table 1. The Examiner states that the application fails to comply with 37 C.F.R. §1.821 through §1.821. The objection is respectfully traversed.

Applicants have amended the present application to include sequence identifiers wherever a nucleic acid or amino acid sequence appears in the present application. In accordance with the cited Sequence Rules, Applicants are submitting herewith, an amended "Sequence Listing" as a paper copy and a "Sequence Listing" in computer readable form, which correspond to the sequence disclosures in the present application. The content of the paper and computer readable copies are the same and do not include new matter. Accordingly, Applicants respectfully request the Examiner to withdraw this objection.

The disclosure is also objected to because there is a hyperlink in the present application at p. 31, line 19. Applicants have removed the hyperlink that appears at page 31 of the present application, as suggested by the Examiner. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection of the Claims under 35 U.S.C. § 101

At pages 3-4, item 9, of the Office Action, claims 4-6, 8, and 10 are rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. The Examiner asserts that claims 4-6, 8, and 10, as written, do not sufficiently distinguish over the nucleic acids SEQ ID NO: 3, 19, and 20 as they exist naturally because the claims do not

particularly point out any non-naturally occurring difference between the claimed products and the naturally occurring products. The rejection is respectfully traversed.

The claims, as presently amended, specify that the nucleic acid of SEQ ID NO: 3 is purified. Support for this amendment can be found at least on page 24 of the present application. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection of the Claims under 35 U.S.C. § 112

At pages 4-5, item 10, of the Office Action, claims 5, 10, and 17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that it cannot be determined what is encompassed by the phrase “hybridizing under stringent conditions” recited in the claims. The Examiner also states that there is insufficient antecedent basis for the phrase “the recombinant vector containing nucleic acid coding for the polypeptide or protein,” recited in claim 9. This rejection is respectfully traversed.

The claims, as presently amended, define “stringent conditions” as a “a condition under which a positive hybridization signal is still observed even after heating at 42 °C in a solution of $6 \times$ SSC, 0.5% SDS and 50% formamide, and washing at 68 °C in a solution of $0.1 \times$ SSC and 0.5% SDS.” Support for this limitation can be found at least at pages 21-22 of the present application. Accordingly, Applicants respectfully submit that the phrase “hybridizing under stringent conditions” as recited in the claims 5, 10, and 17, has been adequately defined.

Applicants also point out that claim 9 has also been amended to depend from claim 8, which provides proper antecedent basis for “the transformant” and “the recombinant vector.”

Accordingly, withdrawal of this rejection is respectfully requested.

Rejection of Claim 17 under 35 U.S.C. § 112, first paragraph

At page 5, item 11, of the Office Action, the Examiner states that claim 17 is rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Examiner states that no nexus has been established between the claimed pharmaceutical compositions and treating multi-drug resistance in cancer patients. This rejection is respectfully traversed.

Claim 17 has been canceled, rendering this rejection moot. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection of Claims 4-8 and 17 under U.S.C. § 112, first paragraph

At page 13, item 12, of the Office Action, claims 4-8 and 17 are rejected under 35 U.S.C. §112, first paragraph. The Examiner is essentially objecting to the recitation in the claims of nucleic acids other than that set forth in SEQ ID NO: 3. This rejection is respectfully traversed.

With respect to the Examiner's assertion that the nucleic acid set forth in SEQ ID NO: 3 can code for a protein or polypeptide that is present in the nucleus of the animal cell, the nucleic acid set forth in SEQ ID NO: 3 can be present both in the nucleus and the cytoplasm.

In order to assist the Examiner, claim 4, upon which claim 8 also depends, has been amended to define the nucleic acid recited in the claims as the nucleic acid set forth in SEQ ID NO: 3 and a nucleic acid strand that is completely complementary to the nucleic acid set forth in SEQ ID NO: 3. As acknowledged by the Examiner in the Office Action, the present application discloses SEQ ID NO: 3. The present application discloses that the term "nucleic acid of the present invention" can include a complementary strand selected from information of the nucleic acid set forth in SEQ ID NO: 3 (page 22). As is also acknowledged by the Examiner, it is

known in the art that the phrase “complementary strands of nucleic acids” can include nucleic acids that are completely complementary to the claimed polynucleotide.

Claim 5 has been amended to define the nucleic acid recited in the claims as a nucleic acid set forth in SEQ ID NO: 3 or a nucleic acid strand that is completely complementary to the nucleic acid set forth in SEQ ID NO: 3, and the phrase stringent conditions has been defined in the claim as a condition under which a positive hybridization signal is still observed even after heating at 42 °C in a solution of 6 × SSC, 0.5% SDS and 50% formamide, and washing at 68 °C in a solution of 0.1 × SSC and 0.5% SDS. Claims 6, 7, and 17 have been canceled. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection of Claims 4-8 and 17 under U.S.C. § 112, first paragraph

At page 19, item 13, of the Office Action, claims 4-8 and 17 are rejected under 35 U.S.C. §112, first paragraph, as lacking an adequate written description in the specification. Essentially, the Examiner states that the specification does not adequately describe the scope of polynucleotides encompassed by the claims. This rejection is respectfully traversed.

In order to assist the Examiner, claim 4, upon which claim 8 also depends, has been amended to define the nucleic acid recited in the claims as the nucleic acid set forth in SEQ ID NO: 3 and a nucleic acid strand that is completely complementary to the nucleic acid set forth in SEQ ID NO: 3. As acknowledged by the Examiner in the Office Action, the present application discloses SEQ ID NO: 3. As is also acknowledged by the Examiner, it is known in the art that the phrase “complementary strands of nucleic acids” can include nucleic acids that are completely complementary to the claimed polynucleotide.

Claim 5 has been amended to define the nucleic acid recited in the claims as a nucleic

acid set forth in SEQ ID NO: 3 or a nucleic acid strand that is completely complementary to the nucleic acid set forth in SEQ ID NO: 3, and the phrase stringent conditions has been defined in the claim as a condition under which a positive hybridization signal is still observed even after heating at 42 °C in a solution of $6 \times$ SSC, 0.5% SDS and 50% formamide, and washing at 68 °C in a solution of $0.1 \times$ SSC and 0.5% SDS. Claims 6, 7, and 17 have been canceled. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection of Claims 4-6 and 17 under 35 U.S.C. § 102(b)

At page 24, item 14, of the Office Action, claims 4-6 and 17 are rejected under 35 U.S.C. §102(b) as being anticipated by AB059622 (October 11, 2001) as evidence by Chano et al. (Oncogene, February 14, 2002, 21:1295-1298, IDS, *see* exhibit 3 for date) and Exhibits 1 and 2. This rejection is respectfully traversed.

Claims 4-6, as presently amended, incorporate the limitations of claim 7, which was not included in this rejection. As such, claims 4-6, as presently amended, are directed to a recombinant vector. AB059622 (October 11, 2001) does not teach or suggest a recombinant vector, as recited in the present claims. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection of Claims 7-10 under U.S.C. §102(a)

At page 25, item 15, of the Office Action, claims 7-10 are rejected under 35 U.S.C. §102(a) as being anticipated by Chano et al. (Oncogene, February 14, 2002, 21:1295-1298, IDS, *see* Exhibit 3 for date) as evidenced by Exhibit 2. This rejection is respectfully traversed.

Three of the authors listed in Chano et al., Chano, Ikegawa, and Okabe, are the also the inventors of the present application. The remaining three authors listed in Chano et al., Kontani,

Baldini, and Saeki, were working under the direction of the present inventors and their contributions were not of an inventive nature. Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 to further establish that the authors of Chano et al. are the inventors of the present application. As such, Applicants respectfully submit that Chano et al. does not qualify as an invention known or used by "others" within the meaning of 35 U.S.C. §102(a). Applicants respectfully request withdrawal of this rejection.

Rejection of Claims 10-17 under 35 U.S.C. § 103(a)

At pages 27-28, item 16, of the Office Action, claims 10-17 are rejected under 35 U.S.C. §103(a) as being unpatentable over AB059622 (October 11, 2001), in view of Mensink et al. (British J. Haematol. (August 1998) 102: 768-774) and further in view of Buck et al. (Biotechniques (1999) 27(3):528-536). The Examiner states that Mensink et al. expressly teaches primer selection using commercially available software for BCR-ABL detection from the BCR-ABL published sequences. The Examiner states that AB059622 provides published sequences for the software program to analyze. The Examiner states that although AB059622 does not teach the particular primers of SEQ ID NO: 19 and 20, it would have been obvious to use the method of Mensink et al. to produce primers selected from the sequences of AB059622. The Examiner states that Buck et al. provides direct evidence that all primers selected according to ordinary criteria would be expected to function. This rejection is respectfully traversed.

As acknowledged by the Examiner, AB059622 does not teach the particular primers of SEQ ID Nos: 19 and 20. Mensink et al. and Buck et al. also do not, alone or in combination, teach or suggest SEQ ID Nos: 19 and 20. With reference to the Examiner's assertion that published sequences may be analyzed by commercially available software for primer selection,

in many cases, one can use the "Primer 3 website" (primer3.sourceforge.net) for this purpose rather than the commercially available software taught in Mensink et al. Simply by knowing the nucleotide sequence information, one can use the "Primer 3 website" to analyze primer design with general versatility. However, only after using the designed primer, can one obtain useful information on whether or not it is applicable to an experiment or clinical. Thus, one cannot determine if a nucleotide sequence is useful, simply because the sequence is known. Accordingly, one of ordinary skill in the art would not be able to arrive at the particular primers of SEQ ID Nos: 19 and 20, simply because of the disclosure of AB059622.

Accordingly, this rejection should be withdrawn.

Should the Examiner deem that any further action by Applicants or Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration of the present application and a timely allowance of the pending claims.

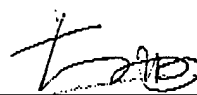
If there are any fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

the article. However, their contributions were not of an inventive nature for purposes of the present application and, therefore, they were not named as inventors. Thus, this is the reason why the authors of the Chano et al. reference differ from the inventors set forth in the present application.

4.) We confirm that the subject matter and work described in Chano et al. is our work, which we invented and disclosed in the present application.

5.) We declare further that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and any such willful false statement may jeopardize the validity of the application or any issuing thereon.

Date:

December 27, 2007
Tokuhiro CHANO

Date:

Dec 27 '07
Shiro IKEGAWA

Date:

Dec 27 '07
Hidetoshi OKABE

Fig. 12

